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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,285	BRETON ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 1/29/07 to claim 9 have been entered. Claims 1-8 and 10-48 have been cancelled in this or a previous reply. Claim 9 only remains pending in the current application and is being considered on its merits. Prior art references not included with this Office action can be found in a prior action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/07 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The claims may be interpreted (see below rejection under 35 U.S.C. § 112, second paragraph) as being broadly drawn to a composition comprising an amount of probiotic lactic acid bacteria or a culture supernatant of any of the same effective to protect a pet from any light energy (hereafter "effective amount"); an effective amount of yeast; and an effective amount of a synthetic or natural carotenoid with or without provitamin A activity (*i.e.*, any carotenoid). Despite the high level of ordinary skill in the microbiology and nutrition arts at the time of the invention, however, the specification in light of the art provides insufficient guidance that the skilled artisan could identify effective amounts of the components across the entire breadth of the claim without undue experimentation.

The specification and the contemporaneous art provide no guidance for identifying an effective amount of culture supernatant for any lactic acid bacterium. The instant specification includes no working examples comprising any culture supernatant in any amount. Furthermore, the specification lists a few particular strains of probiotic

bacteria (see page 4, lines 19-25, and page 9, line 13) for inclusion in the composition (as well as numerous additional species; page 4, lines 10-17), but the working examples direct the skilled artisan to administer about 10^5-10^{12} cfu/day (page 9, lines 14-15 and 33-34). The specification and art provide no evidence, however, that these amounts of each and every probiotic lactic acid bacterium are effective amounts. At page 4, lines 4-8, the specification recites:

> It has now been shown that probiotics do also exert an effect in an individual's body at a location distant from the region in which they colonize it. And particularly, it has been surprisingly found that a composition having a synergistic photoprotective effect on the skin may be obtained by combining into an ingestable [*sic*] carrier, a probiotic micro-organism and a yeast.

No experimental evidence, however, is provided in the specification to support this claim. The working examples merely recite formulations of a few embodiments of the claimed composition.

A thorough search of patent and non-patent literature revealed only three publications on photoprotection by probiotic lactic acid bacteria, all of which publications share at least one inventor with the current application and only one of which, Baur et al. (2002, WO 02/28402), is prior or contemporaneous art[1]. Baur et al. provides a limited working example (pages 8-14, in particular page 12) in which 10^8 cfu/day of either *Lactobacillus johnsonii* (LA1) CNCM I-1225 or *Lactobacillus paracasei* (ST11) CNCM I-2116 are administered orally to mice exposed to ultraviolet light after the mice have been treated with dinitrofluorobenzene (DNFB), a compound characterized by Baur et al. as "known to elicit hypersensitive reactions" in response to UV irradiation (page 12,

[1] Two additional U.S. patent application publications sharing at least one inventor with the instant application were filed after or on the same day as the instant application and provide no additional guidance for determining effective amounts.

paragraph 2). In other words, the findings of Baur et al. do not indicate that oral administration of their *Lactobacillus* strains protects the animals from UV irradiation *per se*, but rather that these bacteria have a protective effect against the immune response to DNFB elicited by UV irradiation. In short, there is no evidence in the specification or the art that any amount of any probiotic lactic acid bacteria would be reasonably expected to have any true photoprotective effect (rather than the mitigation of immune response taught by Baur et al.), much less sufficient teaching to identify effective amounts of each and every probiotic lactic acid bacterial species.

Applicants present a single working embodiment in which formulations for dry and canned dog food are set forth, said formulations comprising one of five particular probiotic lactic acid bacterial strains; one yeast, *S. cerevisiae*; and, in Example 2, unspecified "carotenoids" (Examples 1 and 2 at page 9 of the as-filed specification). While a singular, narrow working embodiment cannot be a sole factor in determining enablement, its limited showing, in light of the unpredictable nature of the art and the lack of direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is drawn to a nutritionally complete pet food comprising "an amount effective to photoprotect a pet of [three components] in an ingestible carrier." It is not clear whether the claim requires an amount of each of the individual components effective for photoprotection or an amount of the entire composition effective for photoprotection. Clarification is required.

The common phrase "an effective amount" may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. *In re Halleck*, 422 F.2d 911, 164 USPQ 647 (CCPA 1970). The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954). The more recent cases have tended to accept a limitation such as "an effective amount" as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim. In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board

held that a pharmaceutical composition claim which recited an "effective amount of a compound of claim 1" without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected. See M.P.E.P. § 2173.05 (c) (III). In this case, neither the specification nor the prior art provides any evidence that probiotic lactic acid bacteria have a photoprotective effect *per se*, much less sufficient guidance that an "effective amount" is particularly defined. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 remains rejected under 35 U.S.C. 102(b) as being anticipated by Shields, Jr. et al. (2000, U.S. Patent 6,156,355; "Shields").

Shields teaches dog food formulations comprising dried yeast, vitamin A, beta carotene, probiotic bacteria (*Lactobacillus acidophilus* and *Enterococcus faecium*), and fermentation extracts of probiotic bacteria (*Bacillus subtilis*, *Aspergillus oryzae,* and *Aspergillus niger*), as well as numerous sources of protein, fat, and fiber (Examples 5 and 6; note in particular column 21, lines 48-49; 50-51; 54; and 60-63).

Shields does not specifically address the photoprotective properties of their food composition. Since the composition of Shields and the instantly claimed composition are

substantially identical in composition, they inherently possess the same properties. M.P.E.P. § 2112 recites, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). As discussed above, applicants do not particularly define the term "photoprotecting effective amount" within the specification, so the composition of Shields reads on the instant claim.

Applicants allege that Shields does not teach any particular amounts of any of the claimed components, therefore Shields cannot anticipate the claimed invention (Reply, page 3, paragraph 2). Applicant argues, "even if all the claimed compositions were included in a pet food formulation, the components could be included in amounts that would be insufficient to provide a photoprotective effect to a pet" (*ibid.*). These arguments have been fully considered, but they are not persuasive.

As discussed at length above in the rejections under 35 U.S.C. § 112, first and second paragraph, the claim does not recite any particular amounts of any of the

components in the composition. The term "effective amount" is not particularly defined, because neither the specification nor the art provide any indication as what might constitute an "effective amount" of each and every probiotic lactic acid bacterium. As such, the term "effective amount" Is indefinite and cannot be interpreted as being limiting in the instant claim. This rejection might be overcome by an amendment to the claim, supported by the specification, limiting the amounts of bacteria, yeast, and carotenoids to be included in the composition to particular numerical values, or by a substantive evidentiary showing that overcomes the rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 USC § 103

The rejections under 35 U.S.C. § 103 are withdrawn in light of the examiner's reconsideration of the enablement issues in this case pertaining to the claim term "effective amount."

The claim is not allowed. The claim is not free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart